

GlaxoWellcome

March 30, 2000

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Management Dockets,
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Food and Drug Administration
HFA-305, Room 1-23
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

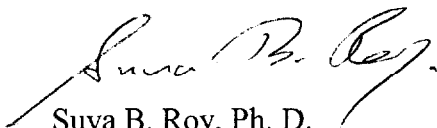
Re: Docket Number: 00D-0087

Dear Sirs:

Please find enclosed GlaxoWellcome's comments on the draft Guidance for Industry -- IND Meetings for Human Drugs and Biologics, Chemistry, Manufacturing, and Controls Information.

Please feel free to contact me at (919) 483-6408 if you need additional information or clarification regarding the comments.

Sincerely,



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00D-0087

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**Comments from GlaxoWellcome on the Draft Guidance for Industry -
IND Meetings for Human Drugs and Biologics
Chemistry, Manufacturing, and Controls**

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General Comments

We commend the Agency for recognizing that a separate IND meeting to address the Chemistry, Manufacturing and Controls (CMC) issues in drug and biologics development program are often required. We also appreciate the Agency's attempt to outline the types of information that should be submitted for a successful IND meeting for CMC issues for drugs and biologics.

Often, teleconferences and videoconferences are faster to arrange than face-to-face meetings. We suggest that the guidance also include options for requesting a teleconference or a videoconference when the agenda items are uncomplicated and amenable for remote conferencing.

Specific Comments

Lines 39 - 42 – We recommend inserting "approval" at the end of the sentence. The revised sentence to read as "The purpose of the pre-NDA or pre-BLA meetings have proper content and format to facilitate Agency review for eventual *approval*."

Lines 53 - 55 – We recommend inserting "relevant" in the sentence. The revised sentence to read as "Sponsors should prepare an information package that includes a brief summary of the currently available *relevant* CMC information development of the drug."

Line 66 – *1. Multidisciplinary Meeting*

In a multidisciplinary meeting adequate time should be allocated for each discipline, specifically we suggest that for CMC issues. Perhaps an acknowledgement of the need to assign time blocks during the development of the agenda would be helpful. While we recognize that one can ask for a separate CMC meeting, such a meeting may not always be needed when there are not enough issues or the issues are relatively uncomplicated.

Line 105 – We suggest replacing "can" in the sentence with "should". The revised sentence to read as "The meeting *should* also include a discussion of hold issues."

Line 164 - C. Focus of Meeting

We suggest adding another bullet topic "Discussion of opportunities and benefits to presubmit the CMC section of the NDA and proposed timing."

We recognize that the topic may be premature for an EOP2 meeting, but it may be helpful in certain circumstances such as potential priority review drugs.

Line 234 - We suggest inserting "critical aspects" in item 1. Revised item 1 to read as "discuss the *critical* aspects of the drug development program."

Lines 234 - 240 - We suggest moving item 5 to item 1 and combining items 2 and 4. The revised paragraph to read as "The purpose of the pre-NDA or pre-BLA meeting is to (1) identify any major unresolved issues that can be problematic in the review and approval process, (2) identify and resolve, if possible, potential refuse-to-file issues, (3) exchange information on the proposed application that will facilitate the review process."

Line 246 - C. Focus of Meeting

We suggest adding another bullet topic "Discussion of opportunities and benefits to presubmit the CMC section of the NDA and proposed timing."

Lines 248 - 250 – We suggest inserting "approval" in the sentence. The revised sentence to read as "Typically the meeting also includes hinder the review and *approval* process."

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